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Attorneys for Plaintiffs

Dear Judge Andrews:

We write on behalf of Novartis to respectfully request that the Court modify the protective order entered in *Novartis v. Noven*, C.A. Nos. 13-527-RGA and 14-111-RGA (“the litigation”) to allow Novartis to use the expert reports of Noven’s expert Dr. Kydonieus from the litigation in *inter partes* review proceedings 2014-00549 and -00550 (“the IPRs”) initiated by Noven and currently pending before the Patent and Trial Appeal Board (“PTAB”). Novartis’s request is time sensitive, as Novartis would like to use Dr. Kydonieus’s litigation expert reports at the deposition of Dr. Kydonieus in the IPRs, which is currently scheduled for **January 13, 2015**.

In both the litigation and the IPRs, Noven alleges that Novartis’s U.S. Patents Nos. 6,335,031 and 6,316,023 are invalid as obvious, and in both proceedings, Noven has introduced expert reports or declarations by Dr. Agis Kydonieus setting forth his opinions concerning the alleged obviousness of the ‘031 and ‘023 patents. However, in the litigation—but not in the IPRs—Dr. Kydonieus’s expert reports also include opinions concerning whether Noven’s accused products infringe the ‘031 and ‘023 patents.

As the Court may recall from Dr. Kydonieus’s December 1, 2014 trial testimony, it is Plaintiffs’ position that Dr. Kydonieus’s infringement opinions are inconsistent with his obviousness opinions. For example, as to infringement, Dr. Kydonieus admitted that his rebuttal expert report included the opinion that one **could not** determine whether an antioxidant was reducing oxidative degradation in Noven’s accused product **without experimental data**. (C.A. No. 13-527, D.I. 154, 219:6-220:1.) By contrast, as to obviousness, Dr. Kydonieus asserted that one **could** conclude that an antioxidant was reducing oxidative degradation in a prior art pharmaceutical formulation in the absence of any experimental data. (*Id.*, 220:22-221:14; 224:23-225:3.)

Novartis would like to create a record in the IPRs of the inconsistencies in Dr. Kydonieus’s litigation expert reports, including at the upcoming January 13, 2015 IPR deposition of Dr. Kydonieus, to permit the PTAB a full and fair opportunity to assess Dr. Kydonieus’s credibility. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48761 (Aug. 14, 2012) (“discovery is a tool to develop a fair record and to aid the Board in assessing the credibility of witnesses”). It is unlikely that Dr. Kydonieus will testify live before the PTAB. Accordingly, this deposition (and any subsequent deposition of Dr. Kydonieus that may be required if he submits a reply declaration in the IPRs) will be Novartis’s only opportunity to cross-examine Dr. Kydonieus.

However, Dr. Kydonieus’s litigation expert reports are marked “confidential,” and the protective order entered in the litigation does not permit the use of documents designated pursuant to the protective order as confidential “for any purpose other than the prosecution and/or defense of the above-captioned case, and in accordance with the terms of this Order,” without specific order of this Court or by written consent of the producing party. (C.A. No. 13-527, D.I. 58, ¶ 1.b.).

To avoid burdening the Court with this issue, on January 5, 2015, Novartis asked Noven for permission to use Dr. Kydonieus’s litigation expert reports at the IPR deposition.¹ On January 6,

¹ Novartis’s counsel Charlotte Jacobsen will take Dr. Kydonieus’s deposition in the IPRs on January 13, 2015. Ms. Jacobsen was out of the country for the holidays and raised this issue with Noven promptly upon returning, when she began preparing for the deposition.

2015, Noven refused, without providing any basis for its refusal. The parties met and conferred on January 7, 2015, at which point Noven maintained its refusal on the bases of relevance, potential confusion, and confidentiality. Accordingly, the parties were unable to reach agreement. Novartis thus hereby respectfully requests that the Court modify the protective order to allow Novartis to use the litigation expert reports of Dr. Kydonieus in the IPRs.

The protective order expressly contemplates and permits modification upon a motion of a party:

This Order may be changed by further order of the Court, and is without prejudice to the rights of any party to move for relief from any of its provisions, or to seek or agree to different or additional protection for any particular material or information. (C.A. No. 13-527, D.I. 58, ¶ 27)

The Court retains jurisdiction even after the termination of the Actions to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may deem appropriate. (*Id.*, ¶ 29)

In addition to the express language of the order, it is settled that courts have the discretion to modify protective orders for good cause. *Pansy v. Borough of Stroudsburg*, 22 F.3d 772, 785-86 (3d Cir. 1994). If the moving party shows good cause, the Court should then balance the interests of public and private parties, including reliance by the original parties on the order, to determine whether good cause still exists. *Id.*

Good cause exists here to modify the protective order.

First, Noven deliberately chose to file the IPRs against the ‘031 and ‘023 patents and to use Dr. Kydonieus as its expert in both the litigation and the IPRs. Noven made those choices knowing full well that Dr. Kydonieus would be cross-examined in the IPRs. Noven should not now be permitted to conceal Dr. Kydonieus’s inconsistent litigation opinions from the PTAB in the IPRs under the pretext of “confidentiality,” particularly when those opinions bear directly on the obviousness arguments asserted by Noven in the IPRs, and are considered in IPR proceedings to be “routine discovery” that Noven should be expected to produce. *See Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48761 (Aug. 14, 2012).² To permit Noven to unilaterally shield this information from the PTAB would be an affront to justice.

Second, any Noven confidential information contained in Dr. Kydonieus’s litigation expert reports can be protected in the IPRs by the simple act of Noven filing a motion to seal, including a proposed protective order. 37 C.F.R. § 42.54. (The PTAB *Trial Practice Guide* goes so far as to provide a default protective order that will be entered “automatically” upon the filing of a motion to seal. *See Office Trial Practice Guide*, 77 Fed. Reg. 48756, 48771 (Aug. 14, 2012).)

² The most blatant inconsistency in Dr. Kydonieus’s opinions in the civil action—that a showing of infringement requires experimental data whereas a showing of obviousness does not, as mentioned above—does not reveal any Noven confidential information. Noven thus cannot reasonably assert that this inconsistency should be concealed from the PTAB on grounds of “confidentiality.”

Noven cannot complain that those readily available protections afforded in IPR proceedings are insufficient to preserve the confidentiality of any Noven confidential information in Dr. Kydonieus's litigation expert reports. Novartis hereby commits to cooperating with Noven to maintain the confidentiality of Dr. Kydonieus's litigation expert reports in the IPR proceedings.³ Moreover, although Mylan's counsel has sought Novartis's and Noven's permission to attend the January 13, 2015 deposition of Dr. Kydonieus, Novartis and Noven have consented to Mylan's attendance, only upon the condition that Mylan's counsel leave the room during any questioning that relates to Noven confidential information. Accordingly, Noven cannot rely on Mylan's presence at the deposition to oppose Novartis's instant request – this argument is a red herring. However, if Mylan's attendance is the impediment to Noven's consent to allow use of the litigation expert reports in the IPRs, then Novartis will withdraw this courtesy to Mylan.

In any event, it is likely that Novartis will only rely on excerpts from Dr. Kydonieus's litigation expert reports in the IPR proceedings, rather than the reports in their entirety. If the parties can agree that those excerpts do not reveal any Noven confidential information, not even a motion to seal will be needed.

Third, if the Court denies Novartis's request to modify the protective order in this case, the interests of both Novartis and the PTAB will be clearly prejudiced: Novartis will be deprived the opportunity to present to the PTAB a full record of the inconsistencies in Dr. Kydonieus's opinions, and the PTAB will be deprived the opportunity to consider those inconsistencies in assessing the credibility of Dr. Kydonieus's testimony and deciding whether the '031 and '023 patents are obvious. As noted above, it is unlikely that Dr. Kydonieus will testify live before the PTAB, and so the January 13, 2015 deposition (and any subsequent deposition on a rebuttal IPR declaration) will be Novartis's only opportunity to cross-examine Dr. Kydonieus. Such clear prejudice outweighs any putative prejudice that Noven may suffer if the protective order in this case is modified in the limited manner requested. As noted above, if the protective order is modified to allow the use of Dr. Kydonieus's litigation expert reports in the IPRs, the parties can cooperate to ensure their continued confidentiality in the IPRs.

In sum, (i) Dr. Kydonieus's litigation expert reports contain inconsistencies that are highly relevant to the obviousness arguments being asserted by Noven in the IPRs, (ii) any Noven confidential information contained in those reports can be adequately protected by available mechanisms in the IPRs, and (iii) the prejudice to Novartis and the PTAB of not being allowed to use those reports in the IPRs outweighs any putative prejudice to Noven. Accordingly, Novartis submits that there exists good cause for modifying the protective order in the litigation to allow Novartis to use the litigation expert reports of Dr. Kydonieus in the IPRs.

Given the time-sensitive nature of Novartis's request, Novartis respectfully requests that the Court enter the enclosed [Proposed] Order prior to January 13. Counsel is available at the Court's convenience in connection with this matter.

³ Mylan has initiated its own IPR proceedings against the '031 and '023 patents, and has moved to join its IPR proceedings with Noven's at the PTAB.

Respectfully Submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: Counsel of record (via electronic mail)

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

	X	
NOVARTIS PHARMACEUTICALS	:	
CORPORATION, NOVARTIS AG,	:	
NOVARTIS PHARMA AG, NOVARTIS	:	
INTERNATIONAL PHARMACEUTICAL	:	
LTD. and LTS LOHMANN THERAPIE-	:	
SYSTEME AG,	:	
	:	
Plaintiffs,	:	C.A. No. 13-cv-527-RGA
	:	C.A. No. 14-cv-111-RGA
v.	:	
	:	
NOVEN PHARMACEUTICALS, INC.,	:	
	:	
Defendant.	:	
	X	

[PROPOSED] ORDER

WHEREAS the Court has considered Plaintiffs’ request to modify the protective order (C.A. No. 13-cv-527-RGA, D.I. 24) entered in the above-captioned cases to permit Plaintiffs to use the expert reports of Dr. Agis Kydonieus from the above-captioned cases in *inter partes* review proceedings IPR2014-00549 and IPR2014-00550 currently pending before the Patent Trial and Appeal Board;

IT IS HEREBY ORDERED that:

1. Plaintiffs’ request is granted;
2. Plaintiffs shall be permitted to use the expert reports of Dr. Agis Kydonieus from District of Delaware C.A. Nos. 13-cv-527-RGA and 14-cv-111-RGA in *inter partes* review proceedings IPR2014-00549 and IPR2014-00550;
3. Plaintiffs and Noven Pharmaceuticals, Inc. shall cooperate in the *inter partes* review proceedings IPR2014-00549 and IPR2014-00550 to maintain the confidentiality of any

confidential material contained in those expert reports, including, if necessary, moving to seal those expert reports.

IT IS SO ORDERED, this __ day of _____, 2015.

Hon. Richard G. Andrews
United States District Court Judge

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on January 7, 2015, on the following counsel in the manner indicated:

BY EMAIL

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Attorneys for Defendant

Dated: January 7, 2015

/s/ Daniel M. Silver
Daniel M. Silver (#4758)